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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,437	03/18/2002	Claudine Elvire Marie Bruck	BC45226	2415

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DECHERT
ATTN: ALLEN BLOOM, ESQ
4000 BELL ATLANTIC TOWER
1717 ARCH STREET
PHILADELPHIA, PA 19103

EXAMINER	
BORIN, MICHAEL L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,437	BRUCK ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *09/2001*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-69 are canceled. Claims directed to elected invention are re-submitted as claims 70-77.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 70-76 are rejected under 35 U.S.C. 112, second paragraph, as being vague and indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is made for the following reasons:

A. Claim 70 (and claims dependent thereupon): the meaning of term "aligned" with respect to "contiguous sequence" is not clear. It is not clear what the contiguous segment of SEQ ID No. 2 is aligned with? What additional limitation the term "aligned" adds to the term "contiguous segment"?

B. Claims 71-76: The claims are vague and indefinite as there are dependent on canceled claims . Examiner assumes that the claims are meant to be dependent on claim 70.

C. Claim 76. It is not clear which "aligned sequence" the claimed polypeptide is supposed to match.

Claim Rejections - 35 U.S.C. § 101/ 112-1

The following is a quotation of the 35 U.S.C. § 101:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The pending claims have been reviewed in light of the the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.
"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.
"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. The following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.
B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. § 101.)
C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility".
D. A method of making a material that itself has no specific, substantial, and credible utility.
E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.
"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

See also the MPEP at §§ 2107 - 2107.02.

4. Claims 70-77 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

The claims are drawn to polypeptides having more than 90% homology to polypeptide SEQ ID No. 2, their fragments, derivatives and fusion proteins comprising thereof. Specification describes that SEQ ID No. 2 is a "putative open reading frame" for polynucleotide SEQ ID No. 1 (p. 36, line 21), and that polypeptide SEQ ID No. 2 is "unrelated to any other known protein" (p. 9, line 21). There is no demonstrated utility for the polypeptide SEQ ID No. 2 itself. No immunological and/or other biological activity for polypeptide SEQ ID No. 2 is demonstrated. Discussion of potential uses on p. 1 is not specific in regard to polypeptide SEQ ID No. 2. Neither, the utility of being immunogenic is either specific or substantial. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context for use. As for demonstration that polynucleotide SEQ ID No. 1 (which encodes polypeptide SEQ ID No. 2) is overexpressed in colon cancer tissues, overexpression of nucleic acids is not directly translated into overproduction of proteins encoded thereby. See, for example, Gygi et al., abstract. The examiner does not find

an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter.

Furthermore, the specification is devoid of showing any utility for a randomly taken fragment of polypeptide SEQ ID No. 2 or for any protein comprising such randomly selected fragment. There is no core structure identified for a fragment required for an identified utility of being able to recognize polypeptide SEQ ID No. 2 .

Further, in regard to the variants claimed that are the result of one or more substitutions, deletions, additions, insertions, notwithstanding the specification's lack of guidance concerning combinatorial mutagenesis, at the time the invention was made, combinatorial mutagenesis was not sufficiently developed to enable one skilled in the art to systematically make even a significant fraction of all the structural embodiments embracing the claimed subject matter. Testing and screening the infinitely vast collection embraced by the claimed subject matter for functional activity would clearly

The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter. Identifying use of the claimed polypeptide would require carrying out further research. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. In addition, there is no well established utility known for polypeptide as claimed. Consequently, the claimed subject matter is not supported by substantial or well established utility.

Claims 70-77 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a substantial or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Claim Rejections - 35 U.S.C. § 112-1 (written description)

5. Claims 70,71,73-77 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Protein CASB619 (SEQ ID No.2) is a protein encoded by polynucleotide SEQ ID No. 1. This exact sequence meets the provision of written description. However, claims 70,71,73-76 as drawn to polypeptides having more than 90% identity to SEQ ID 2, or claim 77, drawn to homologs of SEQ ID No. 2, do not have sufficient description in the specification as description of species present in specification is insufficient to support a highly variable genus. Patent specification must describe claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., Vas-Cath, Inc. *vs* Mahurkar, 935 F.2nd 1555, 1563, 19 USPQ 2d 1111, 1116 (Fed. Cir. 1991). In the instant case, the only products disclosed in the specification is the protein SEQ ID No. 2 itself. No representative species of any other homologs are present. Applicant is advised that absent factual evidence, a percentage sequence similarity of less then 100% over the

entire length is not deemed to reasonably support to one skilled in the art whether the biochemical activity or expression pattern of newly discovered sequence would be the same as that of similar known biomolecule.

Furthermore, in addition to the lack of written description of proteins having >90% identity to protein SEQ ID No. 2, specification lacks written description of a fragments of such proteins. Neither species of such fragments, nor core structure of the fragments required to be able to generate immune response which specifically recognizes polypeptide SEQ ID No. 2 are identified.

Claim Rejections - 35 USC § 102.

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 70,71,73-77 are rejected under 35 U.S.C. 102(b) as anticipated by Baker et al (US 20030004311 A1; application claims priority to provisional applications filed on or about 09/1997).

Baker et al. teaches protein SEQ ID No. 38 which is 99.4 % similar to instant protein SEQ IDS No. 2 (see sequence alignment attached) and nucleic acid SEQ ID No. 37 encoding thereof. See paragraphs [0063-0064]. As said polypeptide SEQ ID No. 38 has high structural similarity, 99.4 %, to full length of SEQ ID No. 2, it will induce an immune response that recognizes instantly claimed polypeptide SEQ ID No. 2.
Further, with respect to claim 73, the referenced polypeptide is viewed as polypeptide comprising a fragment of SEQ ID No. 2.

Specification

7. The specification is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See, for example, pages 34,36. Applicant is requested to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01(b).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571)272-0713. The examiner can normally be reached on 9 am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Borin
Primary Examiner
Art Unit 1631

mlb